

§ 150.101

AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92).

SOURCE: 64 FR 45795, Aug. 20, 1999, unless otherwise noted.

Subpart A—General Provisions

§ 150.101 Basis and scope.

(a) *Basis.* HCFA's enforcement authority under sections 2722 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group health plans.* The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by HCFA using the procedures described in § 150.301 *et seq.*

(2) *Enforcement with respect to health insurance issuers.* The States have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If HCFA determines under subpart B of this part that a State is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in part 146 and part 148 of this subchapter, HCFA enforces them under subpart C of this part.

§ 150.103 Definitions.

The definitions that appear in part 144 of this subchapter apply to this part 150, unless stated otherwise. As used in this part:

Amendment, endorsement, or rider means a document that modifies or changes the terms or benefits of an individual policy, group policy, or certificate of insurance.

Application means a signed statement of facts by a potential insured that an issuer uses as a basis for its decision whether, and on what basis to insure an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

Certificate of insurance means the document issued to a person or entity cov-

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ered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in HIPAA requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

HIPAA requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in § 144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of part 148 of this subchapter. The term "individual health insurance policy" includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of part 146 of this subchapter.

Plan document means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any

State as defined in § 144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

Subpart B—HCFA Enforcement Processes for Determining Whether States Are Failing to Substantially Enforce HIPAA Requirements

§ 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

§ 150.203 Circumstances requiring HCFA enforcement.

HCFA enforces HIPAA requirements to the extent warranted (as determined by HCFA) in any of the following circumstances:

(a) *Notification by State.* A State notifies HCFA that it has not enacted legislation to enforce or that it is not otherwise enforcing HIPAA requirements.

(b) *Determination by HCFA.* If HCFA receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified HCFA that it is implementing an acceptable alternative mechanism in accordance with § 148.128 of this subchapter instead of complying with the guaranteed availability requirements of § 148.120, HCFA's determination focuses on the following:

(1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, HCFA determines whether the State is substan-

tially enforcing the requirements of §§ 148.101 through 148.126 and § 148.170 of this subchapter.

§ 150.205 Sources of information triggering an investigation of State enforcement.

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

(a) A complaint received by HCFA.

(b) Information learned during informal contact between HCFA and State officials.

(c) A report in the news media.

(d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of HIPAA requirements.

(e) Information obtained during periodic review of State health care legislation. HCFA may review State health care and insurance legislation and regulations to determine whether they are:

(1) Consistent with HIPAA requirements.

(2) Not pre-empted as provided in § 146.143 (relating to group market provisions) and § 148.120 (relating to individual market requirements) on the basis that they prevent the application of a HIPAA requirement.

(f) Any other information that indicates a possible failure to substantially enforce.

§ 150.207 Procedure for determining that a State fails to substantially enforce HIPAA requirements.

Sections 150.209 through 150.219 describe the procedures HCFA follows to determine whether a State is substantially enforcing HIPAA requirements.

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If HCFA receives a complaint or other information indicating that a State is failing to enforce HIPAA requirements, HCFA assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, HCFA may contact State officials regarding the questions raised.